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EXAMINER

BAKER, MAURIE GARCIA

ART UNIT

PAPER NUMBER

1627

DATE MAILED: 08/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/871,700

Applicant(s)

Tang et al

Examiner
Maurie Garcia Baker, Ph. D.

Art Unit
1627



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ONE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-25 are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

DETAILED ACTION

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-7, drawn to a compound of formula (I), classified variously depending on the ultimate structure of the compound, for example, in class 548, subclass 488.
 - II. Claims 8-15, drawn to a compound of formula (II), classified variously depending on the ultimate structure of the compound, for example, in class 548, subclass 481.
 - III. Claims 16-19 (in part), drawn to a combinatorial library based on formula (VII), classified variously depending on the ultimate structure of the library members, for example, in class 548, subclass 481 or class 435, DIG 34.
 - IV. Claims 16-19 (in part), drawn to a combinatorial library based on formula (VIII), classified variously depending on the ultimate structure of the library members, for example, in class 548, subclass 469 or class 435, DIG 34.
 - V. Claim 20, drawn to a method of modulating the function of a protein kinase or protein phosphatase, classified variously, for example, in class 435, subclass 21.
 - VI. Claims 21-25, drawn to a method for treating an abnormal condition, classified variously, for example, in class 514, subclass 415.
2. The inventions are distinct, each from the other because of the following reasons:

3. Groups I – IV represent separate and distinct products. They differ in respect to their properties, their use and the synthetic methodology for making them. Therefore, they have different issues regarding patentability and enablement and represent patentably distinct subject matter. The examiner's rationale is set forth below.
4. In the instant case, the compounds in Groups I and II are distinct products having a different core chemical structure (formula (I) vs. formula (II)). This difference in structure will result in differences in properties, use and methods for making (based on different starting materials and/or reactants). Thus the compounds of each of Groups I and II represent patentably distinct subject matter. Similarly, each of the libraries of Groups III and IV are a distinct product having a different core chemical structure (formula (VII) vs. formula (VIII)). This difference in structure will result in differences in properties, use and methods for making (based on different starting materials and/or reactants). Thus the libraries of each of Groups III and IV also represent patentably distinct subject matter.
5. The compounds of Groups I and II differ from the libraries of Groups III and IV because Groups I and II represent distinct (single) compounds while Groups III and IV represent compositions comprising a plurality of compounds. Libraries and single compounds also have different uses and require different methods of making.

6. Groups V and VI are different methods. The methods are different because they use different steps, require different reagents and will produce different products and/or results. They therefore have different issues regarding patentability and enablement and represent patentably distinct subject matter. In the instant case, method of modulating (Group V) is different from the method of treatment (Group VI) because they have different end results and different steps. For example, the method of Group V requires a step of "contacting cells expressing said protein kinase or a protein phosphatase with said compound". This step is not required in the method of treatment of Group VI.
7. Groups I – IV and Groups V & VI are related as product(s) and process(es) of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, each of the products claimed in Groups I – IV could be used in a materially different process of using that product. For example, the compounds could be used in structure-activity relationship studies and the libraries in screening methods. Furthermore, applicant has claimed two different methods of using these products (i.e. the methods of Groups V & VI; see paragraph 6 above); thus, they can clearly be used in different methods.
8. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. Please note that even though

some of these groups could be classified in the same class or subclass, this has no effect on the non-patent literature search. The different products and methods would require completely different searches in these databases (especially for compounds of different core structures), and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

9. This application contains claims directed to patentably distinct species of the claimed invention for **Groups I – VI**. Election is required as follows.

10. If applicant elects the invention of **either of Groups I or II**, applicant is required to elect from the following patentably distinct species. Claim 1 is generic to Group I and claim 8 is generic to Group II.

Species of compound

Applicant is required to elect, for purposes of search, a **specific** compound. That is, selection of each and every variable group to result in a single compound with all atoms and bonds defined.

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the groups have different issues regarding patentability and represent patentably distinct subject matter.

11. If applicant elects the invention of **either of Groups III or IV**, applicant is required to elect from the following patentably distinct species. Please elect *one* species from *each* subgroup below. Claim 16 is generic to each Group.

Species of library (e.g. claim 16 & 19)

Applicant is required to elect, for purposes of search, a specific combinatorial library. That is, selection of each and every variable group of the compounds of the library to result in a single library with all members defined. The "at least five indolinone compounds" should be specifically depicted for the elected library.

Species of aldehyde (e.g. claim 18)

Applicant is required to elect, for purposes of search, a specific aldehyde from those set forth in claim 18 (part (a)).

Species of oxindole (e.g. claim 18)

Applicant is required to elect, for purposes of search, a specific oxindole from those set forth in claim 18 (part (b)).

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the groups have different issues regarding patentability and represent patentably distinct subject matter.

12. If applicant elects the invention of Group V, applicant is required to elect from the following patentably distinct species. Claim 20 is generic.

Species of compound used in the method

Applicant is required to elect, for purposes of search, a specific compound used in the claimed method. That is, selection of each and every variable group to result in a single compound with all atoms and bonds defined.

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the groups have different issues regarding patentability and represent patentably distinct subject matter.

13. If applicant elects the invention of Group VI, applicant is required to elect from the following patentably distinct species. Please elect *one* species from *each* subgroup below. Claim 21 is generic.

Species of compound used in the method

Applicant is required to elect, for purposes of search, a *specific* compound used in the claimed method. That is, selection of each and every variable group to result in a single compound with all atoms and bonds defined.

Species of "abnormal condition"

Applicant is required to elect, for purposes of search, a *specific* "abnormal condition" treated in the claimed method from those set forth in claims 22-25. If cancer is elected, a specific type of cancer from claim 24 should be further elected.

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For species of "abnormal condition" each would have different symptoms/indications. Therefore, the groups have different issues regarding patentability and represent patentably distinct subject matter.

14. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.
15. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and *a listing of all claims readable thereon*, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.
16. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

17. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

18. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

19. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

20. Applicant is also reminded that a 1 - month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday from 9:00 to 6:30 and alternate Fridays.

22. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (703) 308-4537. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.
August 14, 2002



MAURIE GARCIA BAKER, Ph.D.
PATENT EXAMINER